REMARKS/ARGUMENTS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

An Official Action was issued in the present application on March 5, 2003. In response to the Official Action, applicants filed an amendment on June 5, 2003. The Patent Office issued a communication in response to the amendment on August 4, 2003. The communication stated that the clean copy of the claims did not coincide with the marked-up version of the claims. The present amendment seeks to correct this informality. Indeed, the present amendment utilizes the new rules for submitting amendments in the United States Patent and Trademark Office.

Claims 1-34 are pending in the present application. Claims 1, 6-10, and 14-28 have been withdrawn from consideration. Claims 2-4, 11-13 and 29-34 are subject to examination.

Claims 2-4, 11-13, 30, 32 and 34 have been amended to more particularly point out and distinctly claim the present invention. Claims 2-4 and 29-34 are directed to a device for separating CD4-positive cells. Claims 11-13 are directed to a method for separating or detecting human CD4-positive cells. Both the claims directed to the device and method recite that the antibodies are capable of binding to a water-insoluble carrier in

the form of fiber. Support for this recitation may be found in the present specification from pages 28 to 36.

In the outstanding Official Action, claims 2-4, 11-13 and 29-34 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite for failing to particularly point and distinctly claim the subject matter which applicant regards as the invention. It is believed that the present amendment obviates this rejection.

The outstanding Official Action alleged that the term "a device for separating CD4-positive cells using an antibody" was indefinite for not reciting any structural features. However, as noted above, claims 2-4 have been amended to recite that the antibody binds to a water-insoluble carrier in the form of fiber. Thus, it is believed that claims 2-4 are definite to one of ordinary skill in the art.

The outstanding Official Action rejected claims 2, 30, 32, and 34 because the Markush group of antibodies was allegedly indefinite. In the interest of advancing prosecution, the Markush groups found in claims 2, 30, 32 and 34 have been amended and. It is believed that claims 2, 30, 32 and 34 are definite to one of ordinary skill in the art.

The claims were also rejected for containing the recitation "combinations thereof". The Official Action alleged that this recitation was unclear. However, the claims have been

amended to further clarify this term. Thus, it is believed that the present amendment obviates this rejection.

Claims 11-13 were rejected for allegedly setting forth an incomplete method. However, as noted above, claims 11-13 have been amended to recite a method for separating or detecting human CD4-positive cells. The method comprises contacting a cell suspension comprising CD4-positive cells with said water-insoluble carrier, separating said cell suspension and said carrier, and obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface.

Claims 32 and 34 were rejected for allegedly reciting more members of a Markush group than recited in the corresponding independent claim. However, as noted above, claims 32 and 34 have been amended to obviate the contentions pertaining to the Markush groups.

Thus, in view of the above, it is believed that the claimed invention is definite to one of ordinary skill in the art.

In the outstanding Official Action claims 10 and 11 were rejected under 35 USC 102(b) as allegedly being anticipated by GORMAN et al. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that claim 2 was devoid of any structural features other than the antibody. As to claim 11, the Official Action alleged that the

claim did not recite proper method steps. However, as noted above, claim 2 has been amended to recite a device that comprises an antibody that binds to CD4 molecules and a water-insoluble carrier in the form of fiber. Claim 11 has been amended to recite method steps of contacting a cell suspension comprising CD4-positive cells with said water-insoluble carrier, separating said cell suspension and said carrier, and obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface. Thus, it is believed that the claimed invention is directed to a device or method for separating CD4-positive cells, which is simple, rapid and cost-effective.

Applicants respectfully submit that GORMAN et al. fail to disclose or suggest the claimed device and method. GORMAN et al is directed to anti-CD3 antibodies having CDR regions from a rodent antibody grafted into a human framework. Thus, it is believed that GORMAN et al fail to disclose or suggest a device for separating CD4-positive cells comprising an antibody that binds to CD4 molecules and a water-insoluble carrier. As a result, it is believed that GORMAN et al. fail to anticipate or render obvious claims 2 and 11.

Claims 2 and 11 were further rejected under 35 USC 102(e) as allegedly being anticipated by BURKLEY et al. This rejection is respectfully traversed.

As noted above, the Official Action alleged that claim 2 is devoid of any structural features other than an antibody per se. Moreover, the Official Action alleged that the method claims did not recite proper method steps. However, as noted above, claims 2 and 11 have been amended to more particularly point out and distinctly claim the present invention.

It is believed that BURKLEY et al. fail to disclose or suggest a device comprising an antibody, a CD4 molecule and a water-insoluble carrier. Moreover, it is believed that BURKLEY et al. fail to disclose or suggest a method for separating or detecting human CD4-positive cells comprising contacting a cell suspension comprising CD4-positive cells with said water-insoluble carrier, separating said cell suspension and said carrier, and obtaining said water-insoluble carrier which is bound to CD4-positive cells on said cell surface. Indeed, the Patent Office does not contend otherwise.

Applicants believe that the Official Action fails to meet is burden is showing that it would be apparent to one of ordinary skill in the art that the chimeric and humanized antibodies taught by BURKLY et al could be used in the manner as set forth in the claimed invention. Indeed, it is believed that the Official Actions fails to present any evidence that antibodies taught by BURKLY et al may be used in accordance with the claimed invention.

Thus, it is believed that BURKLEY et al. fails to anticipate or render obvious claims 2 and 11.

Claims 2-3 and 11-12 were rejected under 35 USC 102(b) as allegedly being anticipated by HINTON et al. This rejection is respectfully traversed.

The claimed invention is directed to a device and method for separating or detecting CD4-positive cells. The present invention does not require any special or large/expensive devices unlike FACS method or a method utilizing avidin-coated particles/magnetic beads.

While the Official Action alleges that the V-kappa chain sequence and H-chain sequence shown in Figures 2 and 3 of HINTON, respectively, show the sequence identification numbers of the claimed invention, applicants traverse this assertion. It is believed that the amino acids are distinct and non-obvious.

The amino acids of the present invention and HINTON et al. are shown as follows:

ID NO:6 Gln-Gln-Ser-Ser-Glu-Asp-Pro-Pro-Thr

HINTON Gn-Gln-Ser-Tyr-Glu-Asp-Pro-Pro-Thr

ID NO:2 Glu-Ile-Tyr-Pro-Gly-Ser-Gly-Ser-Ala-Tyr-Tyr-Asn-Glu-Met-Phe-Lys-Gly

HINTON Glu-Thr-Tyr-Thr-Gly-Ser-Gly-Ser-Ser-Tyr-Tyr-Asn-Glu-Lys-Phe-Lys-Gly

ID NO:3 Arg-Gly-Thr-Gly-Thr-Gly-Phe-Ala-Tyr

HINTON Arg-Gly-Lys-Gly-Thr-Gly-Phe-Ala-Phe

In view of the above, it is believed to be apparent that the sequences are distinct. As the Examiner is aware, the binding ability of an antibody to antigen may be affected significantly by even the smallest of mutations in CDR regions. As a result, it is believed to be apparent that the sequences of the present invention are clearly different from those set forth in HINTON. That is, the antibodies of the present invention are distinct and non-obvious in view of HINTON'S antibody.

Thus, it is believed that HINTON et al. fails to anticipate or render obvious the claimed invention.

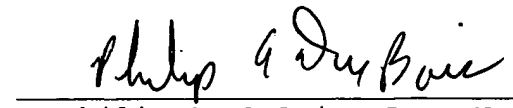
In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 2-4, 11-13, and 29-34, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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